

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

SANDRA HERSHBERGER, et al.

Plaintiffs,

v.

CIVIL ACTION NO. 2:10-cv-00837

ETHICON ENDO-SURGERY, INC., et al.

Defendants.

MEMORANDUM OPINION AND ORDER

On January 19, 2012, the parties in the above-styled civil action appeared before the Court and addressed five pending motions in limine to limit or exclude the testimony of certain expert witnesses. Evidence was presented, and the parties had full opportunity to examine and cross-examine the experts at issue. For the reasons that follow, the motions in limine as to Drs. Ellis, Maxwell, and Sullivan [Dockets 166, 170, and 175] are **DENIED** in their entirety. The motion in limine as to Dr. David [Docket 173] is **GRANTED IN PART** and **DENIED IN PART**. Plaintiffs moved to withdraw the motion in limine as to Dr. Brandon [Docket 293] at the hearing, and the motion to withdraw will be **GRANTED**.

I. FACTUAL BACKGROUND & PROCEDURAL HISTORY

Plaintiffs Sandra Hershberger and David Mitchell filed the instant action in the Circuit Court of Kanawha County, West Virginia, on April 16, 2010. (Docket 1 at 1.) Plaintiffs seek compensatory and punitive damages from Ethicon Endo-Surgery, Inc., and Johnson & Johnson (“Defendants”) for negligence, strict liability, and breach of warranty related to an allegedly

defective stapler used on Plaintiff Hershberger during surgery. (Docket 1-1 at 8-12.) Defendants removed the action to federal court on June 17, 2010, on the basis of diversity of citizenship. (*Id.*) The facts underlying the case are as follows.

Plaintiff Sandra Hershberger¹ underwent a colostomy surgery in September 2008. A colostomy, or Hartmann's procedure, severs the patient's colon and reroutes the proximal, or upper, portion outside of the patient's body. On February 6, 2009, Plaintiff had surgery to reverse the colostomy. A colostomy reversal involves re-connecting the patient's colon to the rectum, which is achieved by forming an "anastomosis," or continuous connection, between the two structures. The first surgery in February 2009 was unsuccessful and is the subject of this litigation. Due to the failure of the first surgery, Plaintiff's surgeons attempted to reverse the Hartmann's procedure a second time on February 6, 2009.²

According to Plaintiff's surgeons, the stapler manufactured by Defendants and used during the first surgery was defective in that it was not loaded with staples. As such, they contend, the surgery was a failure despite their proper execution of the colostomy reversal procedure. In contrast, Defendants maintain that the stapler was loaded with staples and functioned properly during the surgery. Defendants believe that the stapler safety was removed prior to or during its use and one of the surgeons, Dr. Jain, prematurely and negligently fired the stapler. Throughout the course of this litigation, Defendants have argued that radiology films of Plaintiff's bowels clearly and irrefutably demonstrate that surgeon negligence was the cause of the surgery's failure. Defendants

¹ Hereinafter, all references to "Plaintiff" are to Ms. Hershberger, not Mr. Mitchell.

² The second surgery failed as well, although the surgeons admit that the failure was due solely to their incorporating part of Ms. Hershberger's bladder in the attempted anastomosis.

have come forward with expert testimony of this nature. However, Plaintiff also has expert witness interpretations of her radiology films, which dispute Defendants' theory of the case. Plaintiff has additionally produced the testimony of her surgeons, both of whom insist that the stapler was properly utilized but failed.

On August 24, 2011, the Court denied Defendants' motion for summary judgment based on the existence of material factual disputes. (Docket 271.) As of the filing of this Order, there remain pending approximately twenty-five pretrial motions. Addressed in this Order are five of those motions: (1) Plaintiff's Motion in Limine to Exclude or Limit the Testimony of Dr. C. Neal Ellis, Docket 166; (2) Defendants' Motion in Limine to Limit the Testimony of Dr. Damian Maxwell, Docket 170; (3) Defendants' Motion in Limine to Limit the Testimony of Dr. Yadin David, Docket 173; (4) Defendants' Motion in Limine to Limit the Testimony of Dr. James Sullivan, Docket 175; and (5) Plaintiff's Motion in Limine to Exclude the Testimony of Dr. Jeffrey Brandon, Docket 293.

II. DISCUSSION

All five motions in limine relate to the admissibility of expert opinions under Federal Rule of Evidence 702. Pursuant to Federal Rule of Evidence 702,

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.³

³ This version of Rule 702 went into effect on December 1, 2011. The previous version, on which the parties rely, is virtually identical in substance, as the 2011 amendment was merely part of a larger "restyling of the Evidence Rules to make them more easily understood and . . . consistent . . ." Fed. R. Evid. 702, advisory committee note to 2011 amends.

Expert testimony is admissible under Rule 702 if (1) the testimony concerns “scientific, technical, or other specialized knowledge” that (2) will “aid the jury or other trier of fact to understand or resolve a fact at issue.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257 (4th Cir. 1999) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 (1993)). The first prong requires that the Court examine whether the reasoning or methodology underlying the expert’s proffered opinion is reliable; the second prong requires the Court to evaluate whether the proffered testimony is relevant to the issues in controversy. *Daubert*, 509 U.S. at 590-92, 597. In other words, Rule 702 assigns to the trial judge the task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand. *Id.* at 598. In assessing whether an expert’s opinion is sufficiently reliable and relevant, the Court operates as a gatekeeper and conducts a flexible inquiry focusing on the principles and methodology employed by the expert rather than the conclusions reached. *Id.* at 594-95. The Court may consider:

(1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community.

United States v. Crisp, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94); *see also* Fed. R. Evid. 702, advisory committee note to 2000 amends.

Although the Court’s inquiry “must be solely on the principles and methodology [on which an expert relies], not on the conclusions that they generate,” *Daubert*, 509 U.S. at 595, the Court may nonetheless conclude that “there is simply too great an analytical gap between the data and the opinion proffered.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (“[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is

connected to existing data only by the *ipse dixit* of the expert.”). However, as the Supreme Court in *Daubert* stated, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” 509 U.S. at 595; *cf. Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150-51 (1999) (emphasizing that trial judges are entitled to broad discretion when discharging their gatekeeping function, and should not mechanically apply the *Daubert* factors to testimony as if they are a “definite checklist or test.”).

The proponent of expert testimony “must come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998); *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (“The proponent of the testimony must establish its admissibility by a preponderance of proof.” (citing *Daubert*, 509 U.S. at 592 n.10)).

A. *Plaintiff’s Motion in Limine to Exclude or Limit the Testimony of Dr. C. Neal Ellis*

Plaintiff argues that Defendants’ colorectal expert, Dr. C. Neal Ellis, has rendered several opinions that are unreliable and therefore inadmissible because they constitute *ipse dixit* or “because I say so” testimony. (Docket 168 at 10.) In particular, Plaintiff seeks to exclude three of Dr. Ellis’s opinions and two demonstrative surgeries he performed in anticipation of testifying. The three opinions are: (1) that the stapler’s safety must have been inadvertently or prematurely dislodged, whether by a nurse pre-insertion or by Dr. Jain during the course of dialing the stapler out of the “green zone” to release extraneous tissue;⁴ (2) that Drs. Jain and Maxwell would not have been able

⁴ Plaintiff points out that Dr. Ellis’s report and deposition propose separate possibilities for the premature or inadvertent discharge during the first attempted anastomosis on February 6, 2009. The (continued...)

to detect staples in Ms. Hershberger following the first stapler firing without an endoscope; and (3) that Drs. Jain and Maxwell breached the applicable standard of care when they incorporated part of Ms. Hershberger's bladder in the attempted anastomosis during the second firing on February 6, 2009. In attacking these opinions as *ipse dixit* testimony, Plaintiff argues that because Dr. Ellis discredits some of the operative notes and testimony given by Drs. Jain and Maxwell, his opinions are based on "poor expert methodology." (Docket 168 at 12.) Defendants respond that Dr. Ellis's opinions are based on his expertise and experience as a colorectal educator and practitioner and that he relies largely on CT scans depicting the state of Ms. Hershberger's abdomen a month after the surgeries to formulate his opinions. (Docket 219 at 6-8.)

To the extent Dr. Ellis addresses the treating surgeons' reports, he identifies what, in his opinion, are inconsistencies or impossibilities in their accounts of the February 2009 surgeries. Defendants state: "Plaintiffs have not identified any legitimate flaw in [Dr.] Ellis's methodology. Rather, they argue that this expert testimony is inadmissible because it disagrees with the doctors that performed the procedure" (*Id.* at 7.) Defendants are correct. In formulating their opinions, expert witnesses may be called upon to sift through conflicting testimony and data to arrive at an opinion of the most likely course of events. Such determinations of judgment, provided they are well-reasoned and explained, do not render expert testimony inadmissible. Upon review of the parties' respective arguments and the evidence submitted to the Court in support thereof, the Court

⁴(...continued)

report states that in Dr. Ellis's opinion, Dr. Jain fired the stapler outside the green zone, presumably by dialing the stapler out of the green zone to release extraneous tissue, the safety being previously released by Dr. Jain. (Docket 333-5 at 3.) At his deposition, Dr. Ellis suggested that perhaps a nurse or surgical assistant had released the safety, or that Dr. Jain may have inadvertently released the safety prior to or during insertion of the stapler, such that the staples were discharged at some point before being mated with the anvil. Both opinions will be considered for purposes of this Order.

is satisfied that Dr. Ellis's expert opinions regarding the origin of the staples at six to seven centimeters from the anal verge are based upon sufficient facts and are the product of reliable principles and methods. Dr. Ellis's choice to credit some facts contained in the treating physicians' reports and testimony but not other facts is an issue for cross-examination, not a threshold question of admissibility.⁵ Although a factual dispute exists which may serve to discredit Dr. Ellis's opinion, such dispute may be brought out at trial by Plaintiff through cross-examination and the presentation of contrary evidence, namely the treating physicians' recollection of the surgery.

Dr. Ellis also opines that the treating physicians would have been unable to see any staples from the first firing without the use of an endoscope, which all parties agree was not utilized. Plaintiff seeks exclusion of this opinion because "Dr. Ellis admitted that in . . . demonstrative surgeries on pigs, he was able to locate and remove at least one staple without using an endoscope." (Docket 168 at 12.) To formulate his opinion regarding the need for an endoscope, Dr. Ellis states:

[I]t is more likely than not that the surgeons would not have been able to see the staples because: (a) the staples are very small and thin; (b) once the tissue is cut and the stapler is removed, the rectum retracts and would close over the staples; and (c) without properly formed staples to control bleeding, the bleeding from the cut edges of the bowel would have obscured the staples. Under these three conditions, it would be extremely difficult to see staples inside the patient's rectum.

(Docket 333-5 at 4.) Thus, Dr. Ellis draws on his knowledge of and experience with colorectal surgery and circular staplers, including the one at issue in this case, to formulate his opinion regarding the staples' visibility. The mere fact that Dr. Ellis's demonstrative surgery, which is not

⁵ The Court notes that Dr. Ellis's choices to discredit some testimony and data from the treating physicians appears well-founded. For example, Dr. Ellis discredits the testimony that no breakaway washer was present in the stapler at issue. His basis for this opinion is testimony given by the treating physicians that the stapler achieved a complete cut of Ms. Hershberger's bowel. In Dr. Ellis's expert opinion, those two facts are mutually exclusive; he explains why; and he concludes that, in his opinion, a breakaway washer was probably present but overlooked.

meant to precisely replicate the Hershberger surgery, yielded results contrary to his opinion is inconsequential. The opinion will not be excluded.

Plaintiff further seeks to exclude Dr. Ellis's opinion regarding the standard of care applicable to the treating surgeries on the basis that Dr. Ellis has a pending malpractice suit against him in which he disagrees with the allegation that he breached the standard of care applicable to that procedure. In Plaintiff's own words, Dr. Ellis's opinion should be dismissed because he "seeks to hold Dr. Maxwell and Dr. Jain to the 'do as I say, not as I do' standard of care." (Docket 168 at 12.) Defendants are correct to retort that the procedure for which Dr. Ellis is being sued is a separate surgery from the one at issue in this case. Apart from this rationale, whether or not Dr. Ellis breached the standard of care in a separate procedure is irrelevant to the admissibility of Dr. Ellis's opinion.

Finally, Plaintiff seeks to exclude two demonstrative surgeries conducted by Dr. Ellis on the basis that they are too dissimilar to the first surgery on February 6, 2009, to be admissible. (Docket 168 at 12-14.) According to Plaintiff, the dissimilarities include: (1) Dr. Ellis fired the stapler higher in the demonstration pig's pelvis than was the case in the Hershberger surgeries; (2) Dr. Ellis dialed the stapler into the high end of the green zone, rather than the middle of the green zone, as Dr. Jain claims to have done; and (3) Dr. Ellis dialed the stapler out of the green zone after removing the safety. (*Id.* at 13.) In response, Defendants argue that the demonstrations are not meant to recreate or re-enact the first surgery on February 6, 2009; instead, the demonstrations are meant to illustrate that the stapler at issue will perform in a certain manner when manipulated in certain ways, consistent with Dr. Ellis's opinion of the most likely sequence of events. (Docket 219 at 10-11.)

“[D]emonstrations of experiments used to illustrate the principles used in forming an expert opinion are not always required to adhere strictly to the circumstances of the events at issue in the trial.” *Gladhill v. Gen. Motors Corp.*, 743 F.2d 1049, 1051 (4th Cir. 1984) (citing *Brandt v. French*, 638 F.2d 209, 212 (10th Cir. 1981)). In other words, substantial similarity is not a relevant consideration in all circumstances. However, “when the demonstration is a physical representation of how [a device] behaves under given conditions, those conditions must be sufficiently close to those involved in the [incident] at issue to make the probative value of the demonstration outweigh its prejudicial effect.” *Id.* at 1052; *see also Chase v. General Motors Corp.*, 856 F.2d 17, 19-20 (4th Cir. 1988). The Fourth Circuit has also held that “[a]lthough there is a fine line between a recreation and an illustration, the practical distinction ‘is the difference between a jury believing that they are seeing a repeat of the actual event and a jury understanding that they are seeing an illustration of someone else’s opinion of what happened.’” *Hinkle v. City of Clarksburg*, 81 F.3d 416, 425 (4th Cir. 1996) (quoting *Datskow v. Teledyne Continental Motors Aircraft Prods.*, 826 F. Supp. 677, 686 (W.D.N.Y. 1993)). Based on the parties’ representations of the content of Dr. Ellis’s video demonstrations, the Court is unable to hold them inadmissible for failing to meet the substantial similarity requirement set forth above. Furthermore, provided the jury is adequately instructed on the nature of the demonstrations as illustrations of Dr. Ellis’s expert opinions, the Court perceives no admissibility problems. Plaintiff’s arguments are better suited for cross-examination. The motion as to Dr. Ellis is **DENIED** in its entirety.

B. Defendants’ Motion in Limine to Limit the Testimony of Dr. Damian Maxwell

Defendants seek to limit the testimony of Dr. Damian Maxwell, the attending surgeon during Ms. Hershberger’s February 2009 surgeries, “to exclude any opinion that the staples located at 6-7

centimeters from the anal verge were part of the second firing of the stapler.” (Docket 171 at 2.) The motion in limine appears limited to this single opinion. Defendants argue that Dr. Maxwell’s anticipated testimony qualifies as expert testimony rather than treating physician testimony because Dr. Maxwell did not observe any staples inside Ms. Hershberger’s abdomen during the February 2009 surgeries. (Docket 229 at 2-3.) Proceeding from this premise, Defendants continue to argue that Dr. Maxwell’s expert opinions are directly contrary to the CT scans in several respects, as well as indisputable knowledge of human female anatomy. Plaintiff responds that Dr. Maxwell’s testimony is indeed that of a treating physician rather than an expert witness. (Docket 194 at 8.) The rationale for Plaintiff’s argument is simple: Dr. Maxwell’s testimony is derived from his personal observations during the course of treating Ms. Hershberger. (*Id.*) To the extent Dr. Maxwell is considered an expert witness, and Defendants’ assertion that his opinions are contrary to the “objective evidence” in the case therefore becomes relevant, Plaintiff contends that there is a factual dispute as to what the CT scans depict and the origin of the pertinent staples. (*Id.*)

After considering the evidence presented in the parties’ briefing and the record,⁶ it appears to the Court that Dr. Maxwell’s opinion regarding the origin of the staples located at six to seven centimeters from Ms. Hershberger’s anal verge is a product of his experience and observations in the role of treating physician. The simple fact that Dr. Maxwell never visually observed staples deploy at six to seven centimeters from the anal verge does not require a finding that Dr. Maxwell’s opinion is expert testimony, as Defendants suggest. Dr. Maxwell’s testimony is comprehensive as to the February 2009 surgeries (as well as the two other surgeries), and based on his observations in their entirety, a conclusion that the relevant staples were deposited from the second firing rather

⁶ Plaintiff decided not to present Dr. Maxwell at the January 19, 2012, hearing.

than the first is entirely reasonable. More specifically, Dr. Maxwell stated that Dr. Jain maneuvered and discharged the stapler appropriately during the first stapling, that he inspected the staple site immediately following the stapling, and that he observed no staples (formed or unformed) at that time. Based on those observations and his first-hand knowledge that only two staplers were discharged in February 2009, Dr. Maxwell is able to opine that the staples in Ms. Hershberger at six to seven centimeters from the anal verge resulted from the second stapler firing, which he knows (first hand) to have deposited staples in Ms. Hershberger's gastrointestinal tract. Pursuant to the record before the Court, then, Dr. Maxwell's testimony on this point is not expert in nature. *See* Fed. R. Evid. 701 (lay testimony includes, *inter alia*, "opinions . . . rationally based on the witness's perceptions").

Moreover, even assuming Dr. Maxwell's opinion is properly regarded as expert testimony, Defendants' arguments must fail. The CT scans are, of course, objective evidence in a sense: they present a relatively accurate and reliable depiction of Ms. Hershberger's body on the date the scans were conducted. However, to further assert, as Defendants do, that one expert witness's interpretation of the scans is objective and irrefutable evidence, such that any differing interpretation must be unreliable to the extent of inadmissibility, goes too far. CT scans are often difficult to "read" or interpret (hence the need for expert testimony), and physicians may disagree as to what a given CT scan depicts. Defendants' argument is, at base, a bald assertion that Dr. Maxwell's opinion regarding the origin of the staples located six to seven centimeters from the anal verge may not be considered by a jury because Defendants' experts believe the CT scans to be contradictory evidence (although Plaintiff's radiologist disagrees on multiple grounds). The Court will not exclude Dr. Maxwell's opinion on this point for such a reason. "[T]he trial court's role as

gatekeeper is not intended to serve as a replacement for the adversary system.” Fed. R. Evid. 702, advisory committee note to 2000 amends. (citing *United States v. 14.38 Acres of Land Situated in Leflore County, Miss.*, 80 F.3d 1074, 1078 (5th Cir. 1996)). Instead, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 595. Dr. Maxwell’s opinions, whether lay or expert, are fertile ground for cross-examination and the presentation of contrary evidence. The motion to limit his testimony is **DENIED**.

C. Defendants’ Motion in Limine to Limit the Testimony of Yadin David

Defendants seek to exclude Plaintiff’s manufacturing defect expert, Yadin David, on two grounds. First, Defendants argue that Dr. David fails to draw on his education and experience as a biomedical engineer in formulating his opinions, which constitute *ipse dixit* testimony. Second, they argue that Dr. David’s opinion that Ms. Hershberger’s surgery was unsuccessful due to a manufacturing defect is contradicted by “objective” radiographic evidence. (Docket 174 at 8-12.) Dr. David was not offered at the hearing on these motions, and the Court is therefore confined to rely on the briefing related to Defendants’ motion in limine and Dr. David’s reports in executing its role as gatekeeper. Dr. David’s supplemental report discloses the following opinions in this case:

As they pertain to the facts of this case, my opinions are as follows: First, Ethicon Endo-Surgery, Inc. (“Ethicon”) manufactured and marketed the PROXIMATE ILS Curved Intraluminal Stapler device that was not reasonably safe for its intended use and presented an unreasonable biomedical engineering risk in connection with its use in Sandra Hershberger’s surgery, particularly with respect to the lack of staples in the stapler. The Ethicon device was manufactured and marketed with defects and failed to warn potential end users about its defective state and the risks resulting from its use under this condition. Ethicon failed to conduct itself as a reasonably prudent manufacturer and distributor of medical devices.

(Docket 333-3 at 3.) However, according to Plaintiff's memorandum in response to the motion in limine, Dr. David opines that "based upon the lack of staples in the stapler, the stapler was defective." (Docket 199 at 11.)

At the outset, it must be noted that it is unclear to the Court whether Defendants seek to exclude all of Dr. David's testimony on the basis that he fails to assist the trier of fact under Rule 702, or whether they simply seek to exclude his opinion that, "based upon the lack of staples in the stapler [reported by the treating physicians], the stapler was defective." The motion in limine is styled as one to limit the testimony of Dr. David, rather than to exclude Dr. David entirely, so the Court will presume that Defendants do not seek to wholly exclude Dr. David.

Defendants challenge the opinions (1) that a stapler without staples is defective and (2) that this stapler had no staples when fired. The thrust of Defendants' arguments is that Dr. David's opinions fail to draw upon his expertise or experience as a biomedical engineer, and that they not only fail to assist the trier of fact, they infringe on the province of the jury to decide from legitimate testimony whether the stapler was indeed unloaded and therefore defective. (Docket 174 at 6-8.) In plain terms, Defendants argue that Dr. David simply credits the testimony of Drs. Jain and Maxwell that no staples were present in the stapler at issue and, regurgitating Ethicon's own product information, states that a stapler without staples is defective. It appears that Plaintiff (perhaps inadvertently) agrees. Plaintiff's responsive memorandum states:

Dr. David opined that based upon the lack of staples in the stapler, the stapler was defective. . . . As a matter of common sense, a single use surgical stapler which is not loaded with staples is defective. There can be no dispute of that fact. . . . Dr. David's opinion is exactly the same as that reflected in Defendant Ethicon's engineering documents and the testimony of its corporate representatives—if a stapler is not loaded with staples, the stapler is defective.

(Docket 199 at 12.)

Defendants are correct. Dr. David's opinion that a stapler without staples is defective does not draw on any specialized knowledge, education, or experience as a biomedical engineer. As Plaintiff plainly admits, his conclusion is a matter of common sense. The motion is **GRANTED** to the extent it seeks to preclude Dr. David from testifying that "based upon the lack of staples in the stapler [reported by the treating physicians], the stapler was defective." The motion is further **GRANTED** to the extent it seeks the exclusion of any opinion premised on Dr. David's belief that the first stapler contained no staples. Unlike the physician-experts in this case, Dr. David possess no specialized knowledge, skill, expertise, or education that would permit him to reach a more informed or helpful conclusion (than the jury) regarding what transpired in the relevant surgeries.

Defendants also urge the Court to exclude Dr. David's opinions because "abundant objective evidence proves [Dr. David's testimony] to be objectively wrong." (Docket 174 at 9.) To the extent this alternative basis for exclusion is not rendered moot by the Court's rulings above, it is **DENIED**. Conflicting interpretations of the radiographic images in this case will be presented to the jury, and the Court will not, therefore, exclude testimony on the basis that one interpretation is more credible or "objectively accurate" than the other. The motion as to Dr. David is **GRANTED IN PART** and **DENIED IN PART**.

D. Defendants' Motion in Limine to Limit the Testimony of Dr. James Sullivan

Defendants next seek to exclude the opinion of Dr. James Sullivan, Plaintiff's colorectal surgery expert, that the staples located in Ms. Hershberger at approximately six to seven centimeters from the anal verge resulted from the second surgery on February 6, 2009. (Docket 176 at 9-15.) Defendants also seek to exclude any of Dr. Sullivan's expert opinions related to any radiology

imaging, as well as any opinion purporting to establish a causal link between alleged product defect and Ms. Hershberger's surgical infection. (*Id.* at 15-16.)

1. Staples at Six to Seven Centimeters

Defendants make three arguments against the admissibility of Dr. Sullivan's opinions regarding the staples located at six to seven centimeters from the anal verge: (1) they were not timely disclosed under Federal Rule of Civil Procedure 26(a)(2); (2) they are based upon an unreliable source, namely Plaintiff's radiology expert, Dr. Mark Younis; and (3) they are objectively wrong.

Regarding Defendants' first argument, Rule 26(e)(2) of the Federal Rules of Civil Procedure provides that "[a]ny additions or changes to [an expert report under Rule 26(a)(2)(B) or expert deposition] must be disclosed by the time the party's pretrial disclosures under Rule 26(a)(3) are due." The Federal Rules provide that Rule 26(a)(3) disclosures "must be made at least 30 days before trial" unless the court orders otherwise. Fed. R. Civ. P. 26(a)(3)(B). The Court's August 17, 2010, scheduling order provides that Rule 26(a)(3) disclosures may be supplemented until the conclusion of the final settlement meeting on July 6, 2011. (Docket 6 at 2-3.) According to Plaintiff, she complied with the Federal Rules by timely supplementing her expert disclosures on May 31, 2011. (*See* Docket 114, 213-9.) That document states:

Dr Sullivan is an expert who will testify about the foreseeable and necessary additional medical treatment required by Sandra Hershberger as a result of the malfunction of the Ethicon stapler; whether or not the treating physicians breached the standard of care; and with respect to the surgical procedures at issue, including the locations at which staples were used and/or removed. Dr. Sullivan will testify consistent with his February 14, 2011, March 14, 2011, and April 1, 2011 disclosures, reports, and attachments thereto, as well as his May 5, 2011 deposition (including any forthcoming errata) and exhibits - all of which are herein incorporated by reference.

(Docket 213-9 at 2.) Plaintiff's supplemental disclosures were timely. Thus, the Court agrees with Plaintiff, and accordingly **DENIES** Defendants' motion in limine to the extent it seeks exclusion of Dr. Sullivan's testimony on the basis of untimely disclosure under Rule 26.⁷

Defendants also argue that Dr. Sullivan's opinions related to the staples at six to seven centimeters from the anal verge are based on unreliable source data—namely, Plaintiff's radiology expert, Dr. Younis. Defendants state that “Plaintiff's [sic] . . . acknowledge that Dr. Younis's opinions regarding the staple lines [including staples at six to seven centimeters from the anal verge] were incorrect.” (Docket 176 at 11.) Defendants argue that because Dr. Younis has filed an errata sheet to substantively correct the contents of his deposition, “Dr. Sullivan's opinions, originating from his conversation with Dr. Younis, are thus based upon an unreliable source.” (*Id.*) In short, Defendants argue that Dr. Younis did not know what he was talking about when he spoke with Dr. Sullivan immediately before Dr. Sullivan's deposition, and because Dr. Sullivan relied upon Dr. Younis's allegedly faulty knowledge of the procedure at issue, his opinions related to the staples at six to seven centimeters from the anal verge are also unreliable and must be ruled inadmissible at trial under *Daubert*.

Defendants' argument assumes that Dr. Sullivan's opinions related to the staples located at six to seven centimeters derive entirely from Dr. Younis's deposition testimony and the pair's telephone conversation prior to Dr. Sullivan's deposition. However, Dr. Sullivan stated at the hearing on these motions that he relied on medical records of Plaintiff's hospital stay, the relevant

⁷ Defendants also argue they were “sandbagged” at Dr. Sullivan's deposition because his opinions related to these staples were not previously disclosed. (Docket 176 at 10.) To the extent Defendants may have been prejudiced by this fact, which appears questionable based on thorough questioning of Dr. Sullivan on the subject at his deposition, they were free to seek leave to depose Dr. Sullivan a second time.

operative notes and radiographic reports, as well as his conversation with Dr. Younis immediately prior to Dr. Sullivan's deposition. His expert disclosures confirm that he relied, *inter alia*, upon "Ms. Hershberger's imaging and reports" in formulating his opinions. (Docket 333-11 at 1.) Dr. Sullivan also stated that, in his conversation with Dr. Younis, "Dr. Younis was describing what he saw on a CAT scan . . . [and][w]hat I was offering was the anatomy as to what's descending colon, what's rectal stump, what's sigmoid colon, and kind of explaining in my words the actual operation." Dr. Sullivan further stated that Dr. Younis reported finding three sets of staples in Ms. Hershberger, just as Dr. Sullivan expected from conducting his independent, *post facto* differential diagnosis, although Dr. Younis mistakenly referred to the set of staples appearing at the top of the rectum as appearing in the descending colon. When pressed for a concise explanation of the disagreement between Dr. Younis and himself, Dr. Sullivan stated:

We agreed on the location of the staples in our conversation, we both agreed, but in [Dr. Younis's] early description we had a slight disagreement, meaning we—I guess using anatomic—he said descending colon and I was saying distal bowel at the rectal stump. In other words, the part of the colon just above the rectum is the sigmoid, not the descending colon [as Younis was referring to it].

Based on the above information, the Court cannot find, as a matter of law, that all of Dr. Sullivan's opinions related to the staple line at six to seven centimeters from the anal verge are inadmissible due to his interactions with Dr. Younis, who has allegedly changed his opinions in the meantime. Such attacks on the veracity and accuracy of Dr. Younis's opinions, and Dr. Sullivan's by extension, are appropriately conducted on cross-examination.

Defendants' third argument against Dr. Sullivan's opinions regarding the staples at six to seven centimeters from the anal verge is identical to an argument lodged against Dr. Maxwell. The CT scans in this case are the "smoking gun," Defendants say, constituting objective and irrefutable

evidence that the first stapler was loaded. However, the radiologists' opinions in this case are directly opposed to one another, and the Court is unconvinced that the CT scans so clearly depict unformed staples, as Defendants assert. Additionally, the colorectal surgeons dispute whether the second firing can be responsible for the staples in both Ms. Hershberger's bladder and rectum. The resolution of these disputes is properly left to the jury, as the Court has determined none of the testimony to be inadmissible under *Daubert*.

2. *Radiology Opinions*

Defendants next move to exclude "any opinion testimony of Dr. Sullivan based upon the radiology imaging." (Docket 176 at 15.) The entirety of Defendants' motion to exclude Dr. Sullivan's opinions related to the CT scans⁸ is as follows:

Rule 702 of the Federal Rules of Evidence permits opinion testimony by experts when the witness is "qualified as an expert by knowledge, skill, experience, training, or education." By Dr. Sullivan's own admission, he is a "cut and sew surgeon" without expertise in radiology. Dr. Sullivan clearly does not qualify as an expert in radiology under Rule 702

(*Id.*) Contrary to Defendants' argument, certified radiologists are not the only physicians to possess "knowledge, skill, experience, training, or education" relating to radiographic evidence. *Cf. Cannelton Indus. v. Frye*, 93 F. App'x 551 (4th Cir. 2004) (upholding ALJ's finding that board certified radiologists were better qualified to read x-rays than non-radiologist physicians). At the hearing, Dr. Sullivan testified that he reviews x-rays and CT scans in practicing colorectal medicine on a daily basis. To the extent Defendants believe the opinion of their radiologist to be more

⁸ The Court is unaware of whether such opinions exist, as Dr. Sullivan did not testify at the hearing regarding any interpretation of the CT scans he may have rendered.

accurate and his credentials more impressive than Dr. Sullivan's, they are welcome to demonstrate such to the jury.

3. *Surgical Infection Causation*

Finally, Defendants move to exclude Dr. Sullivan's opinion that the alleged product defect and related complications were responsible for Ms. Hershberger's post-surgical infection on two grounds. First, Defendants argue that the opinion must be excluded because Dr. Sullivan has cited no published authority to support his opinions. Second, Defendants argue that because Dr. Sullivan "cannot testify to a reasonable degree of medical probability that [increased surgery duration and contamination risks] made it more likely than not that Ms. Hershberger would suffer a post-surgical infection, this opinion should be precluded by [the] Court." (Docket 176 at 16.) As to the former argument, Rule 702 does not impose a rigid requirement that expert opinions be supported by published literature. The advisory committee's note to Rule 702 suggests a number of factors for a district court to consider in assessing an expert's reliability as part of its gatekeeping function, including: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted. *See Fed. R. Evid. 702*, advisory committee note to 2000 amends. While Dr. Sullivan mentioned in his deposition that "the literature" supports his opinion that increased surgery duration and an increase in risk classification lead to increased risk of surgical site infection, he was unable to cite to specific articles or published authorities. (Docket 176 at 6.)

Contrary to Defendants' argument, an expert's inability to point to published literature supporting his opinions will not render those opinions inadmissible on reliability grounds. Such was

the holding in *Daubert* itself. 509 U.S. at 589 (holding that Rule 702 overruled the requirement that an opinion must gain general acceptance in order to qualify as expert testimony; instead general acceptance and peer review are merely two factors to be considered). In this case, Dr. Sullivan stated that he based his opinion regarding Ms. Hershberger's surgical site infection not only on "the literature," but also upon his education and experience as a colorectal surgeon. Dr. Sullivan stated that he treats patients on a daily basis as a "cut and sew surgeon," and has done so for over twenty years; his credentials as a board certified colorectal surgeon with an internship, residency, and fellowship following medical school remain unchallenged; he testified that risk classifications and surgery duration are taught as risk factors to surgical site infection in standard medical education; and he provided the Court with a well-reasoned explanation of why duration and risk classification impact the likelihood of a patient developing a post-operative infection. Based on the foregoing considerations, the Court concludes that Dr. Sullivan's knowledge and experience render his testimony reliable and adequately demonstrate that his testimony is based on good grounds.⁹ *See generally Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003) (holding the same in similar circumstances).

⁹ The Court is cognizant that the fact "that an expert may be qualified by experience does not mean that experience, standing alone, is a sufficient foundation rendering reliable *any* conceivable opinion the expert may express." *United States v. Frazier*, 387 F.3d 1244, 1261 (11th Cir. 2004) (emphasis in original). As the advisory committee notes to Rule 702's 2000 amendments explain, "[i]f the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *See* Fed. R. Evid. 702, advisory committee notes to 2000 amends. Based on his testimony at the hearing, and giving consideration to the advice in the advisory committee's notes, the Court is unwilling to exclude Dr. Sullivan's testimony for lack of published literature in support.

As to the second argument Defendants raise regarding Dr. Sullivan's infection-related testimony, the proper standard for expert testimony on the subject of causation was enunciated in Syllabus point 3 of the West Virginia Supreme Court's opinion in *Hovermale v. Berkeley Springs Moose Lodge No. 1483*, 271 S.E.2d 335 (1980): "Where a physician is testifying as to the causal relation between a given physical condition and the defendant's negligent act, he need only state the matter in terms of a reasonable probability." *See also* Syl. pt. 1, *Pygman v. Helton*, 134 S.E.2d 717 (1964) ("Medical testimony to be admissible and sufficient to warrant a finding of proximate cause of an injury is not required to be based upon a reasonable certainty that the injury resulted from the negligence of the defendant. All that is required to render such testimony admissible and sufficient is that it should be of such character as would warrant a reasonable inference that the injury in question was caused by the negligent act or conduct of the defendant."). In their reply brief, Defendants argue that it is dispositive that Dr. Sullivan "did not state to a reasonable degree of medical probability that such increased risk was a substantial factor in causing Ms. Hershberger's surgical site infection." (Docket 246 at 9.) However, at the hearing on these motions, Dr. Sullivan opined that the increased risk of infection caused by the alleged product defect and related complications was a substantial factor in leading to Ms. Hershberger's post-surgical infection. Dr. Sullivan also stated that he holds that opinion to a reasonable degree of medical certainty as a colorectal surgeon. Following West Virginia precedent, the Court declines to exclude Dr. Sullivan's testimony on this basis. The motion in limine regarding Dr. Sullivan is **DENIED** in its entirety.

E. Plaintiff's Motion in Limine to Exclude the Testimony of Dr. Jeffrey Brandon

At the January 19, 2012, hearing, counsel for the plaintiffs orally moved to withdraw the Motion to Exclude the Testimony of Dr. Jeffrey Brandon [Docket 293]. The motion to withdraw is **GRANTED**, and the Clerk is **DIRECTED** to terminate the motion in limine as to Dr. Brandon.

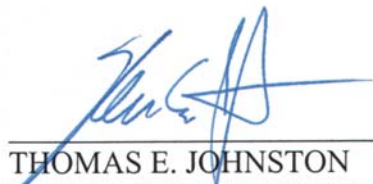
III. CONCLUSION

The motions in limine as to Drs. Ellis, Maxwell, and Sullivan [Dockets 166, 170, and 175] are **DENIED** in their entirety. The motion in limine as to Dr. David [Docket 173] is **GRANTED IN PART** and **DENIED IN PART**.

IT IS SO ORDERED.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 15, 2012



THOMAS E. JOHNSTON
UNITED STATES DISTRICT JUDGE